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### REMARKS

Applicants have reviewed the Office Action mailed October 13, 2009. Applicants have not amended the claims in response to the Office Action. Thus, claims 1-4 and 15-18 remain pending in the application. Claims 5-8 had previously been cancelled, and claims 9-14 had previously been withdrawn from consideration.

#### *Claim Rejections – 35 USC § 102/103*

Claims 1-4 and 15-18 stand rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Agnihotri et al. (1996, Indian J. Experimental Biology, 34, 712-715) and as evidenced by Li (1996, Malawai: Country Report to the FAO International Technical Conference on Plant Genetic Resource, Leipzig).

Agnihotri et al. is a journal article concerned with and entitled “A Novel Approach To Study Antibacterial Properties Of Volatile Components Of Selected Indian Medicinal Herbs.” This journal article has previously been cited in combination with other references in two prior office actions mailed April 21, 2009 and October 8, 2008.

In the office action dated October 8, 2008, Agnihotri et al. was cited in support of rejection of then pending claims 1-8 under 35 U.S.C. 102(b). In that office action, Agnihotri et al. was mischaracterized as disclosing the use of whole plant of *Cinnamomum zeylanicum*, including the fruit being extracted. In response to the October 8, 2008 office action, Applicants noted that the article states, “This paper presents a study of the effect of volatile components of the commonly used components of Indian medicinal herbs using a novel approach.” See Agnihotri et al., at p. 712. In view of this statement of the scope of that study, Applicants submitted then and submit now that Agnihotri et al. teaches only the use of commonly used components of *Cinnamomum zeylanicum* and contains no teaching or suggestion of the use of

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the unconventional parts (i.e., fruits) of *Cinnamomum zeylanicum*, hexane extraction of dried or powdered fruits, or a composition comprising an antibacterial fraction obtained by hexane extraction of powdered ripe fruit of *Cinnamomum zeylanicum*.

In the office action mailed April 21, 2009, rejection of the claims under 35 U.S.C 102 (b) was not maintained based upon Agnihotri et al. which Applicants' submit was in recognition of the deficiencies of Agnihotri et al., specifically those identified in the immediately preceding paragraph above. In the April 21, 2009 office action, Agnihotri et al. was again cited, however, as a supporting reference in support of a rejection of claims under 35 U.S.C. 103(a), with Jayaprakasha being cited as the primary reference in conjunction with Tunist and Li. Agnihotri et al., was expressly cited for its teaching of the use of hexane to extract a bioactive fraction from the dried and powdered *Cinnamomum zeylanicum*. As Agnihotri et al. only teaches the use of conventional parts of the *Cinnamomum zeylanicum* plant, it did not then and does not now teach the use of unconventional parts of the *Cinnamomum zeylanicum* plant, specifically the fruit.

Applicants submit that there is nothing in the teaching of Agnihotri et al. that would suggest to one skilled in the art that fruit of *Cinnamomum zeylanicum* contained bioactive components and that such components could be extracted from the fruit.

In the pending Office Action, the Application has again been rejected under 35 U.S.C 102(b) and 35 U.S.C 103(a) and again in reliance upon the teaching of Agnihotri et al. as evidenced by Li. Applicants here reiterate their above arguments regarding the teachings of Agnihotri et al. Agnihotri et al. does not stand for the proposition nor does it contain any teaching of the use of the fruit of the *Cinnamomum zeylanicum* plant. Contrary to the Examiner's statement that the *Cinnamomum zeylanicum* referenced in Agnihotri et al. "would inherently contain the fruit because the whole plant would include the fruit," it is clear that

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Agnihotri et al. did not use the whole plant and more importantly did not use the fruit in their study. Applicants submit that this statement of the teachings of Agnihotri et al. is far broader than can be supported by the disclosure and the statements of Agnihotri et al. about the scope of their study and the use of conventional parts of *Cinnamomum zeylanicum*.

As previously noted, the abstracts of Agnihotri et al. expressly state that the purpose of their study was "to develop a novel approach to assess the antibacterial activity of few aromatic herbs like *Eugenia caryophyllus*, *Thymus vulgaris*, *Cinnamomum zeylanicum*, *Cuminum cyminum* . . .". (Emphasis Added) Applicants submit that this statement does not encompass the entire structure of each listed plant species; and rather was limited to study of conventional plant parts. Further, at page 712, Agnihotri et al. state, "This paper presents a study of the effect of volatile components of the commonly used parts of Indian medicinal herbs." It is known to those skilled in the art that the commonly used parts of the *Cinnamomum zeylanicum* is the bark.

The Office Action states that *Cinnamomum zeylanicum* would inherently contain fruit because the whole plant would include the fruit without citation in support of the statement. As previously noted, Agnihotri et al. does not teach the use of the whole *Cinnamomum zeylanicum*, only its conventional parts. The fruit of the *Cinnamomum zeylanicum* plant is not a conventional part or a source known for its antibacterial effects. The Examiner has not cited any reference supporting the proposition that the fruit is a conventional or "commonly used" part of Indian medicinal herbs.

The Office Action states that the drying process inherently means that the extract is dried, where the moisture content is between 5-6% and cites to Li, page 18, 3.3 Storage Facilities in support of the statement. The purpose of the Examiner citation of Li is unclear. Li does not

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teach, suggest or address the drying of a hexane extract. Here is what Li says at page 18, 3.3

Storage Facilities:

The Malawi Plant Genetic Resources Centre seed store use upright deep freezers and it is intended for long term storage of both base and active collections. Seed samples are dried to 5-6% moisture content (on dry weight basis) for oil seeds and between 6-7% mc for cereals and they are put in sealed aluminum foil bags and stored in deep freezers which are operated at -18° C.

The Malawi Country Report (Li) is here talking about the moisture content of dried oil seed and cereals. There is no relevance whatsoever to the drying or storage of an extract of any kind, whether that of Agnihotri et al. or that of Applicants. Further, Agnihotri et al. do not teach drying of their extract; as can be seen at page 712. Agnihotri et al. only teaches filtering the extract and storing the extract at 10° C. The only mention of drying is prior to the powdering of the conventional parts of the *Cinnamomum zeylanicum* and other Indian medicinal herbs. So, neither Agnihotri et al. nor Li provide any disclosure or teaching of a extract that has been dried for any purpose, as in the invention, and neither provide any basis for rejection of the claims relative to moisture content.

The Office Action states, "The claims are drawn to an antibacterial bioactive composition comprising hexane extract of *Cinnamomum zeylanicum* as the active ingredient, within a product-by-process claim." Further, the Office Action states that Agnihotri et al. teaches a composition consisting of an extract of *Cinnamomum zeylanicum* as the active ingredient which appears to be identical to Applicants' claimed composition, including the claimed levels of antibacterial bioactive fraction. Further, it states that the reference and the claimed invention

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both were prepared with similar powdering of *Cinnamomum zeylanicum*, and extraction and concentrations steps (oils were filtered and hexane evaporated) and that the claimed invention is anticipated by the reference. In the alternative, the Office Action states that even if the two compositions are not identical the differences between that which is disclosed in the reference and claimed by Applicants are considered to be so slight that the referenced composition is likely to inherently possess characteristics of the claimed composition and therefore would have been obvious to one skilled in the art.

Given the documented differences between parts of *Cinnamomum zeylanicum*, the suggestion that the composition obtained by Applicants is necessarily the same as that obtained by Agnihotri et al. is unfounded. References of record provide clear evidence that the composition of extracts obtained from different parts of the *Cinnamomum zeylanicum* plant are different.

In their study published in 1997, Jayaprakasha et al. documented their study of the chemical composition of the volatile oils of the fruits of the *Cinnamomum zeylanicum* blume. Based on their 1997 study, Jayaprakasha et al. stated, "In conclusion, the essential oils from fruits of *C. zeylanicum*, which contains trans-cinnamyl acetate and  $\beta$ -caryophyllene as the major components, is distinct from that of other parts of the plant such as the leaf, root bark and stem bark." Their 1997 study further documented differences in chemical compositions of volatile oils obtained from fruit grown in different regions. Jayaprakasha et al. later documented their study of the chemical composition of the volatile oils from *Cinnamomum zeylanicum* bud. In that study published in 2002, Jayaprakasha et al. observed, "The volatile oils of buds of *C. zeylanicum* contains  $\alpha$ -bergamotene (27%) and  $\alpha$ -copaene (23.1%) as the major compounds. This is different from oils of other parts of *C. zeylanicum* such as the leaf, root bark, stem bark,

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flowers and fruits. But there are some similarities as it contains many other compounds that are present in other oils as well.” Kaul et al. conducted a study of the volatile constituents of essential oils isolated from different parts of cinnamon (*Cinnamomum zeylanicum* blume), specifically tender twigs bearing buds, flowers and fruits, pedicels of buds and flowers, buds and flowers, pedicels of fruit, and fruit. Regarding the results of their investigation, Kaul et al. stated, “The investigation has shown that different parts of the cinnamon plant yield oils of widely differing composition, providing opportunity for perfumers and flavourists to choose oils according to their requirements.” Based upon these and other studies documented in references of record in this case, one skilled in the art would not presume or conclude that the an extract from commonly used part of the *Cinnamomum zeylanicum* and the fruit of *Cinnamomum zeylanicum* would contain the identical constituents nor that an extract of these parts would yield identical compositions having identical properties.

Applicants submit that references of record provide clear documentation that the various parts of *Cinnamomum zeylanicum* do not contain identical constituents or identical amounts of common constituents.

Applicants have discovered that an antibacterial composition can be obtained from the non-convention parts of *Cinnamomum zeylanicum*, specifically the fruit. There is no teaching of this in the references cited or of record in this case. There is no basis for the statement that the extract of Agnihotri et al. is identical to Applicants’ claimed composition and its level of antibacterial fraction.

In Agnihotri et al., the antibacterial effect of their extract from the commonly used parts of *Cinnamomum zeylanicum* was expressed in relative terms, -, +, ++, +++, and +++++, which respectively correlated with 0%, 25%, 50%, 75% and 100% inhibition rates. Agnihotri et al.

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tested the inhibitory effect of their extract at a concentration of  $1.78 \times 10^{-3}$  g/ml (1780 ppm). In their Examples 1-5, Applicants documented the minimum inhibitory concentration (MIC), the concentration of their extract needed to obtain 100% inhibitory effect, in parts per million (ppm). Amongst the bacteria tested by Agnihotri et al. and Applicants, there were only three commonly tested species: *Bacillus subtilis* (B.subtilis), *Pseudomonas aeruginosa* (P.aeruginosa), and *Staphylococcus aureus* (S.aureus). Additionally, Applicants tested two additional species of *Bacillus* bacteria: *B.cereus* and *B.coagulans*. Comparison of results obtained is presented in the below table:

	Example 1	Example 2	Example 3	Agnihotri	Example 4	Agnihotri	Example 5	Agnihotri
Conc. (ppm)	250	300	300	1780	200	1780	500	1780
% Inhibition	100%	100%	100%	25%	100%	0%	100%	50%
B.subtilis		X		X				
B.cereus	X							
B.coagulans			X					
P.aeruginosa					X	X		
S.aureus							X	X

Tests in Applicants' Examples were conducted for 20-24 hours. Tests by Agnihotri et al. were conducted with results being documented after 24 hours and 48 hours; however, no increase in inhibitory effect was seen between 24 hours and 48 hour. From the above table it can be seen, that in each instance, Applicants' extract resulted in 100% inhibition at substantially lower concentrations than tested by Agnihotri et al., ranging from about 3.5 to about 7 times less.

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Phrased differently, even at concentration ranges from 350% to 700% greater, 100% inhibition could not be achieved by Agnihotri et al.'s extract. This clearly belies the statement that the composition of Agnihotri et al. would "intrinsically have antibacterial effect at 200 to 500 ppm." The data of Agnihotri et al. provides no basis for the conclusions that the instantly claimed extract composition is anticipated. Rather, the data clearly shows surprisingly different properties, demonstrating that the two compositions are not identical.

The claims are drawn to a composition comprised of a hexane solvent extracted bioactive fraction obtained from the fruit of *Cinnamomum zeylanicum*. Applicants' extract is not obtained from conventional parts of *Cinnamomum zeylanicum*, e.g., the bark, as in Agnihotri et al., and distinguishes from Agnihotri et al. by expressly claiming a composition comprising a hexane extracted bioactive fraction obtained from fruit of *Cinnamomum zeylanicum*. The teaching of Agnihotri et al. on this point is clear and it does not extend beyond the conventional parts of *Cinnamomum zeylanicum*. Further, the comparative data illustrates that the compositions are not the same given that Applicants achieve 100% inhibitory effect while with significantly greater concentrations of Agnihotri et al.'s extract comparable inhibition could not be obtained.

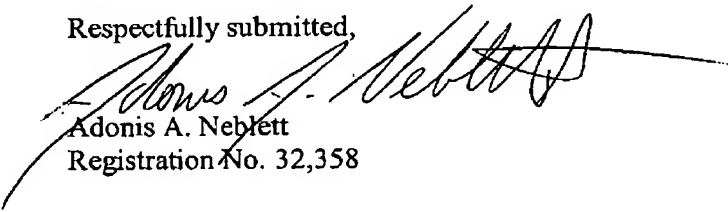


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### CONCLUSION

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested. The Commissioner is hereby authorized to charge any additional filing fees required to Deposit Account No. 061910. On behalf of the Applicants, the undersigned plans to contact the Examiner to schedule a telephonic interview in hopes that an interview would be useful to advance prosecution.

Respectfully submitted,



Adonis A. Neblett  
Registration No. 32,358

Customer No. 22859  
FREDRIKSON & BYRON, P.A.  
200 South Sixth Street, Suite 4000  
Minneapolis, MN 55402-1425 USA  
Telephone: (612) 492-7000  
Facsimile: (612) 492-7077

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